JUL 1 0 2001

K011311

ELECTRONIC INDUSTRY AND TRADE CO, LTD

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30 APR 2001

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD
TURAN GUNES BUL KONRAD AD CAD
59/1 SANCAK CANKAYA, 06550
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TEL:+90 312 491 6010
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CONTACT PERSON: CENGİZ KABAKCI
ASSISTANT GENERAL MANAGER

2. Device Identification

Proprieatary Device Name:	**URO***logic* Urological Table
Common/Generic Device Name:	Fluorocsopic Imaging System, Urological Table
Classification Name:	SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED
Product Code:	90 JAA
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.1650

3. *Substantial Equivalence*

The **URO***logic* Urological Table is substantially equivalent to the following currently marketed devices:

- OEC Uroview 2600 (K940295)
- Liebel-Flarsheim Hydradjust IV (K943581)

4. *Description of Device*

URO*logic* is a universal fluoroscopic x-ray diagnostic system intended for use in providing x-ray imaging of patient with an undertable image intensifier. The system consists of a floor mounted tilting patient support table, x-ray generator, x-ray tube assembly, image intensifer and the tv system. The system is operated via tableside control panel, foot/handswitches and x-ray control panel. The system comes with a tripple mode image intensifier, a CCD camera with one frame memory, x-ray tube with housing and an image monitor.

The tabletop can be moved motorized in longitudinal and lateral directions. The table can be tilted –15 to +87 degrees. Cranial movement of connected x-ray tube and image intensifer assembly gives the operator the advantage of scanning without moving patient. System has a stationary grid and casette holder for radiographic films. Patient positioning and other accessories are also provided.

5. *Intended Use*

URO*logic* is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to urologic and endoscopic procedures. The system may be used for other imaging applications at physician's discretion.

6. *Technological Characteristics*

URO*logic* Urological Table employs the same technological characteristicsas the predicate devices. This device is intended for the same applications as the currently marketed predicate devices. All systems are image intensified x-ray imaging systems with an overtable x-ray tube assembly. Like the predicate devices, **URO***logic* Urological Table consists of basic the basic patient suport table, and standard system components: x-ray generator, x-ray tube, Image Intensifier, TV system and monitor(s).

7. *Standards*

The **URO***logic* is designed in accordance with the product safety and performance requirements established in the following standards given in Table-1:

IEC 60601-1-1	Medical Electrical Equipment-Part 1 General Requirements for Safety" with Ammend 1 and 2
IEC 60601-1-2	Medical Electrical Equipment-Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
IEC 60601-1-3	Medical Electrical Equipment-Part 1 General Requirements for Safety-3. Collateral Standard: General Requirements for radiation protection in diagnostic x-ray equipment
IEC 60601-2-7	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of high-voltage generators of diagnostic x-ray generators
IEC 60601-2-28	Medical Electrical Equipment, X-Ray Tubes and X-Ray Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of associated equipment of x-ray equipment
IEC 60601-2-46	Medical Electrical Equipment, Safety of Operating Tables

Table-1 Product Performance and Safety Standards

Results of performance and compliance testing conducted at factory and independent test organizations on **URO***logic* system, indicates conformance to all applicable performance standards promulgated by FDA for these systems.

8. *Conclusion*

Based on the comparison to other devices in technological characteristics and intended use, the **URO***logic* Urological Table is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Cengiz Kabakci
Assistant General Manager
PCK Electronic Industry and Trade Co, Ltd.
Turan Gunes Bul Konrad AD CAD
59/1 Sancak, Cankaya, 06550
ANKARA TURKEY

Re: K011311
(URO) Logic (Urology x-ray table)
Dated: April 30, 2001
Received: April 30, 2001
Regulatory Class: II
21 CFR 892.1980/Procode: 90 IXR
21 CFR 892.1650/Procode: 90 JAA

Dear Mr.Kabakci:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

Applicant: PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD

TURAN GUNES BUL KONRAD ADENAUER CAD
59/1 SANCAK, CANKAYA
O6550, ANKARA
TURKIYE

510(k) NUMBER: K011311

DEVICE NAME: **URO***logic* Urological Table

INDICATIONS FOR USE:

URO*logic* is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures

Prescription Use √

David A Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011311